

Zimmer Spine - 510(k) – PathFinder NXT System – Section 5. 510(k) Summary

**510(k) SUMMARY****Zimmer Spine PathFinder NXT® Minimally Invasive
Pedicle Screw System**

Date of Summary Preparation: September 12, 2013

Submitter: Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, MN 55439

Establishment Registration Number: 2184052

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Trade Name: PathFinder NXT® Minimally Invasive Pedicle
Screw System

Device Name (Common Name): Orthosis, Spinal Pedicle Fixation, For
Degenerative Disc Disease; Orthosis,
Spondylolisthesis Spinal Fixation; Orthosis,
Spinal Pedicle Fixation

Device Classification: Class III

Product Code(s): NKB, MNH, MNI

Regulation Number: 21 CFR § 888.3070

Regulation Description: Pedicle screw spinal system

Predicate Devices:

For clarification purposes, this is the initial submission for this device modification and has not previously been submitted/withdrawn via a 510(k), PMA or de novo pathway. The modified *PathFinder NXT® Minimally Invasive Pedicle Screw System* is claimed to be substantially equivalent to the following legally marketed predicate devices:

<i>PathFinder NXT® Minimally Invasive Pedicle Screw System</i> Predicate Device Name	Submission ID Number	Clearance Date
PathFinder NXT® Minimally Invasive Pedicle Screw System	K121671	July 18, 2012
PathFinder NXT® Minimally Invasive Pedicle Screw System	K100845	September 21, 2010

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<i>PathFinder NXT® Minimally Invasive Pedicle Screw System</i> Performance Predicate Device Name	Submission ID Number	Clearance Date
Sequoia® Pedicle Screw System including SpeedLink II™ Transverse Connector System	K082032	October 6, 2008
Synergy D2 Spinal Implant	K984578	March 23, 1999
Titanium TSRH® Spinal System (Screws)	K946348	August 7, 1995

General Device Description:

The existing, commercially available *Zimmer Spine PathFinder NXT® Minimally Invasive Pedicle Screw System* ("PathFinder NXT System") consists of various screws, rods and associated accessories and is intended to provide temporary stabilization following surgery to fuse the spine. The PathFinder NXT screws are polyaxial cannulated designs with a range of spinal rod lengths. The PathFinder NXT System allows the surgeon to place polyaxial pedicle screws either through an open or mini-open procedure. The percutaneous insertion rods are for minimally invasive procedures. The PathFinder NXT System is designed to aid in the surgical correction of several types of spinal conditions and intended only to provide stabilization during the development of a solid fusion with a bone graft. These implants are intended to be removed after the development of a solid fusion mass.

Additionally, the PathFinder NXT System includes instrumentation to facilitate the implantation of the PathFinder NXT implants.

Indications for Use:

When intended for pedicle screw fixation from T1-S1, the indications include immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion.

As a pedicle screw system placed between L3 and S1, the indications include Grade 3 or Grade 4 spondylolisthesis, when utilizing autograft or allograft, when affixed to the posterior lumbosacral spine, and intended to be removed after the solid fusion is established.

Summary of Technological Characteristics:

The subject *Zimmer Spine PathFinder NXT® Minimally Invasive Pedicle Screw System* shares the same technological characteristics as its predicate device, *Zimmer Spine PathFinder NXT® Minimally Invasive Pedicle Screw System*. The characteristics include the same design, same materials, same range of sizes, substantially equivalent performance characteristics and the same intended use.

The subject and predicate *PathFinder NXT® Minimally Invasive Pedicle Screw System* both consist of polyaxial screws, titanium rods, and the instruments necessary to implant the spinal system. All implant components are made from medical grade titanium alloy (Ti6Al4V ELI) per ASTM F136 and unalloyed titanium per ASTM F67.

The *PathFinder NXT® Minimally Invasive Pedicle Screw System* is designed to aid in the surgical correction of several types of spinal conditions, as stated in the section above. The *PathFinder NXT® Minimally Invasive Pedicle Screw System* consisting of polyaxial screws and titanium rods is intended to provide temporary stabilization following surgery to fuse the spine. The subject and predicate systems are provided non-sterile, are for single use only and are intended to be removed after solid fusion has occurred.

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Summary of Performance Testing:

The *PathFinder NXT® Minimally Invasive Pedicle Screw System* is substantially equivalent to the predicate devices in design, materials, function and intended use.

The performance testing included components of the subject *PathFinder NXT® Minimally Invasive Pedicle Screw System*, which were reviewed and tested appropriately for design verification, design validation, biocompatibility and sterilization. The test results conclude the subject *PathFinder NXT® Minimally Invasive Pedicle Screw System* to be substantially equivalent to its predicate devices, *PathFinder NXT® Minimally Invasive Pedicle Screw System*, *Sequoia® Pedicle Screw System* including *SpeedLink II™ Transverse Connector System*, *Synergy D2 Spinal Implant* and *Titanium TSRH® Spinal System (Screws)*.

- Bench testing (static compression bending, static torsion testing, and dynamic compression bending per ASTM F1717 and static axial grip, static torsion grip, and static flexion-extension bending per ASTM F1798) for implants, polyaxial screws, and rods confirmed the product performance of the subject *PathFinder NXT® Minimally Invasive Pedicle Screw System* is suitable for its intended use.
- Cadaver lab testing of the subject *PathFinder NXT® Minimally Invasive Pedicle Screw System* to evaluate human factors regarding the combination of instrument design changes and labeling design changes, as well as interaction with implants to confirm the substantial equivalence of the changes compared to the identified predicate devices.
- Biocompatibility testing ensured the subject *PathFinder NXT® Minimally Invasive Pedicle Screw System* materials are biocompatible after manufacturing based on the minor design changes made in comparison to the predicate devices.
- Sterilization, Dry Time and Cleaning testing ensured the subject *PathFinder NXT® Minimally Invasive Pedicle Screw System* steam sterilization, cleaning and dry time requirements and instructions are substantially equivalent to the predicate devices.

Substantial Equivalence:

Zimmer Spine considers the subject *PathFinder NXT® Minimally Invasive Pedicle Screw System* product performance to be substantially equivalent to its predicate devices, *PathFinder NXT® Minimally Invasive Pedicle Screw System* and *Sequoia® Pedicle Screw System* including *SpeedLink II™ Transverse Connector System* because there are no changes to the product performance specifications or device functional scientific technology.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Zimmer Spine, Incorporated
Mr. Jonathan Gilbert
Director, Regulatory Affairs
7375 Bush Lake Road
Minneapolis, Minnesota 55439

November 25, 2013

Re: K132884

Trade/Device Name: PathFinder NXT® Minimally Invasive Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: September 12, 2013
Received: September 13, 2013

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Zimmer Spine - 510(k) – PathFinder NXT System – Section 4. Indications for Use Statement

Indications for Use

K132884

510(k) Number (if known): _____

Device Name:

Zimmer Spine PathFinder NXT® Minimally Invasive Pedicle
Screw System

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K132884